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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09 711,782      | 11 13 2000  | Rex M. Bitner        | 16026 9264          | 7178             |

23810 7590 11 25 2002

MICHAEL BEST & FRIEDRICH, LLP  
ONE SOUTH PINCKNEY STREET  
P O BOX 1806  
MADISON, WI 53701

EXAMINER

RILEY, JEZIA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 11 25 2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

# Office Action Summary

Application No.

09/711,782

Applicant(s)

BITNER ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-51 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 13-16, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 9-12, 17 and 20-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Remarks*

1. Applicants' arguments and amendments, filed on 10/10/02, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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3. Claims 1-4, 7, 8, 13-16, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (6,027,945).

Smith et al. discloses methods of isolating biological target materials using silica magnetic particles. The methods provide for isolating biological target materials, particularly nucleic acids, such as DNA or RNA or hybrid molecules of DNA and RNA, from other substances in a medium using silica magnetic particles. The methods involve forming a complex of the silica magnetic particles and the biological target material in a mixture of the medium and particles, separating the complex from the mixture using external magnetic force, and eluting the biological target material from the complex. The preferred embodiments of magnetic silica particles used in the methods and kits of the present invention are capable of forming a complex with at least 2  $\mu\text{g}$  of biological target material per milligram of particle, and of releasing at least 60% of the material from the complex in the elution step of the method. The methods produce isolated biological target material which is substantially free of contaminants, such as metals or macromolecular substances, which can interfere with further processing or analysis, if present. First, a mixture is formed comprising the medium including plasmid DNA, the siliceous-oxide coated magnetic particle, and a chaotropic salt. The concentration of chaotropic ions in the mixture formed is preferably between about 0.1 M and 7 M, but more preferably between about 0.5 M and 5 M. The concentration of chaotropic ions in the mixture must be sufficiently high to cause the biological target material to adhere to the silica magnetic particles in the mixture, but not so high as to substantially denature, to degrade, or to cause the target material to precipitate out of the mixture.

The biological target material isolated using the method can be obtained from eukaryotic or prokaryotic cells in culture or from cells taken or obtained from tissues, multicellular organisms including animals and plants; Cells will be lysed and the lysate usually processed in various ways familiar to those in the art to obtain an aqueous solution of DNA or RNA, to which the separation or isolation methods are applied. The DNA or RNA, in such a solution, will typically be found with other components, such as proteins, RNAs (in the case of DNA separation), DNAs (in the case of RNA separation), or other types of components.

4. Claims 5, 6, 9-12, 17, 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 24-51 are allowed.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

November 22, 2002



JEZIA RILEY  
PRIMARY EXAMINER